

### Remarks

Claims 20-31, 34-36, and 40-44 are currently pending. Claims 20-31, 34-36, and 40-44 stand rejected.

#### Claim Rejections – 35 USC 102 (e)

Claims 20-31, 35-36 and 40-44 stand rejected under 35 U.S.C. 102(e) as being anticipated by Williams (US 5,731,284) with evidence by Mayer et al (US 5,352,683). Applicant respectfully submits that Williams cannot serve as a proper anticipatory reference, as it does not teach the claimed invention. Williams does not teach use of GDNF in the treatment of pain, but rather teaches administration of GDNF to a subject suffering from neurodegeneration such as occurs in diseases such as Parkinson's, Alzheimer's disease, and Amyotrophic Lateral Sclerosis.

The Examiner argues that administration of GDNF as taught by Williams inherently alleviates pain. The claimed invention recites a method comprising administration *to a human suffering from pain* a composition comprising an amount of GDNF effective to alleviate the pain in the human. Applicant submits that in order for the claimed invention to be inherently anticipated by Williams, *all* patients suffering from neurodegeneration must suffer from pain. The Examiner has not provided evidence that this is the case. Instead, the Examiner cites Mayer et al, which merely remarks that “Neuropathic pain is thought to be a consequence of damage to peripheral nerves *or* to regions of the central nervous system” and that “...abnormal functioning of pain-related regions of the nervous system *can* also occur with chronic inflammatory conditions such as certain types of arthritis and metabolic disorders such as diabetes.” (column 1, emphases added). The claimed invention cannot be inherently anticipated by the teachings of Williams in combination with the speculative remarks in Mayer et al.

Claims 20-31, 35-36 and 40-44 stand rejected under 35 U.S.C. 102(e) as being anticipated by Lin et al (WO 93/06116) with evidence by Mayer et al (US 5,352,683). Lin et al teaches a method of administering GDNF in a therapeutically effective amount to prevent or treat nerve damage such as that occurs in Parkinson's patients. The Examiner argues that administering GDNF according to the teaching of Lin et al “would inherently on (*sic*) the neuropathic pain.” Assuming that the Examiner meant that administering GDNF according to

the teaching of Lin et al would inherently *alleviate* the pain, Lin et al could only inherently anticipate the claimed invention if *all* patients with nerve damage suffered from pain. The Examiner has not shown this to be the case. Furthermore, Lin et al does not teach administering GDNF in any amount effective to alleviate pain, or, nor does it provide any guidance for determining the amount or amounts that would be effective to alleviate pain, even if pain were present in the patient to which GDNF is administered. Because Lin et al does not anticipate each and every limitation of the claimed invention, which includes “an amount of GDNF effective to alleviate pain in the human,” it is not a proper anticipatory reference.

Claims 20-31, 35-36 and 40-44 stand rejected under 35 U.S.C. 102(e) as being anticipated by Yan et al (WO 93/06116) with evidence by Mayer et al (US 5,352,683). Yan et al teaches the treatment of retinal ganglion cell injury such as glaucoma using GDNF. Yan et al does *not* also teach, as the Examiner suggests, the treatment of “physical injury, ischemia, neurotoxin, metabolic diseases such as diabetes, and neurodegenerative diseases such as Parkinson’s using GDNF.” These other conditions were only mentioned in the Background section of Yan et al as possible contributory causes of nerve damage. Yan et al does not teach, nor claim to teach, treatment of all such conditions.

The Examiner again cites Mayer et al as teaching that metabolic disorders such as diabetes may be related to abnormal functioning of the pain related regions of the nervous system, and argues that “GDNF is administered and would inherently on (*sic*) the neuropathic pain associated with diabetes or other metabolic disease or neurotoxins.”

Assuming that the Examiner meant that GDNF administration would inherently alleviate neuropathic pain associated with diabetes or metabolic disease, Applicant respectfully disagrees. Because Yan et al does not teach treatment of metabolic diseases such as diabetes, the teaching in Mayer et al with regard to metabolic disorders is irrelevant to the teaching of Yan et al. Administering GDNF in accordance with the teaching of Yan would not inherently treat pain associated with diabetes or other metabolic disorders, since the teachings of Yan et al are directed to treatment of retinal ganglion cell injury or degeneration. Thus, one cannot combine the teachings of Mayer et al with those of Yan et al to anticipate the claimed invention of administering GDNF to a *human suffering from pain* in an amount *effective to alleviate the pain*. The only guidance as to dosing or other parameters provided by Yan et al is directed to treatment of retinal ganglion cell injury or degeneration.

For reasons stated above and for reasons previously filed but have not been rebutted, Applicant respectfully requests that this rejection be withdrawn.

## **CONCLUSION**

Applicant again thanks the Examiner for his careful review of the case. Based on the Remarks presented above, Applicant respectfully submits that Claims 20-31, 35, 36, and 40-44 are now in condition for allowance. A Notice to this effect is respectfully requested.

Please charge any fees that may be associated with this matter, or credit any overpayments, to our Deposit Account No.: 03-1721.

Respectfully submitted,

/BHJarrell/

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Brenda Herschbach Jarrell, Ph.D.  
Reg. No.: 39,223

Choate, Hall & Stewart LLP  
Patent Group  
Two International Place  
Boston, MA 02110

Tel: 617-248-5000  
Fax: 617-248-4000

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